



IPW

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Malcolm PEET et al.

Group Art Unit: 1617

Serial No.: 10/776,226

Examiner: Not Yet Assigned

Filed: February 12, 2004

Atty Dkt. No.: P64234US4

For: HIGHLY PURIFIED EPA AND OTHER  
EPA DERIVATIVES FOR PSYCHIATRIC AND  
NEUROLOGICAL DISORDERS

Customer No.: 00136

**SECOND INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

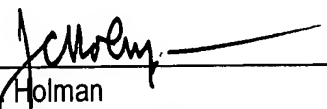
As a means of complying with the duty of disclosure under 37 CFR §1.56, and in accordance with 37 CFR §§1.97 and 1.98, Applicant(s), through the undersigned attorney, submits this Information Disclosure Statement. The patents submitted herewith are listed on the attached Form PTO-1449 and copies are attached.

The documents listed on the Form PTO-1449 were cited in an Office Action issued in a pending U.S. application. A copy of the relevant pages of the Office Action and a copy of the PTO-892 are attached.

In accordance with 37 CFR §1.97(b)(3), this Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits of the above-identified application.

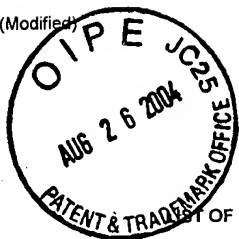
Respectfully submitted,

JACOBSON HOLMAN PLLC

By:   
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Date: August 26, 2004  
JCH/JC



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# STATEMENT OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT

APPLICANT: PEET et al.  
 SERIAL NO.: 10/776,226  
 FILING DATE: February 12, 2004

GROUP ART UNIT: 1617  
 ATTY. DOCKET NO.: P64234US4  
 TODAY'S DATE: August 26, 2004

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## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE (If Appropriate)
	AA	5,837,731	11-17-98	Vaddadi			
	AB	6,555,700 B1	4-29-2003	Horrobin et al.			

## FOREIGN PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	Translation	
							(Yes)	(No)
	AC							
	AD							
	AE							
	AF							
	AG							
	AH							
	AI							

## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AJ	
	AK	
	AL	
	AM	
	AN	
	AO	
	AP	
	AQ	
	AR	

EXAMINER	DATE CONSIDERED
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).



DEBIT NOTE REQUEST FORM

REQUESTED BY: JCH/JC/clc  
CLIENT NO.:/CASE NO.: 1398/P64234US4  
CLIENT NAME: REDDIE & GROSE  
DEBIT NOTE DATE: 8/26/04  
TEXT FOR SERVICES: IDS:

(TO PROFESSIONAL SERVICES IN CONNECTION WITH THE ABOVE-CAPTIONED APPLICATION, INCLUDING PREPARING AND FILING AN INFORMATION DISCLOSURE STATEMENT; DOCKETING; AND REPORTING)

DISBURSEMENT DESCRIPTION: FOR DISBURSEMENTS INCURRED, INCLUDING ANY DUPLICATING, POSTAGE, AND MISCELLANEOUS ADMINISTRATIVE EXPENSES.

CHARGE BREAKDOWN BY BILLING CODES:

ATTORNEY	AMOUNT
1. JCH	\$50.00
2. JC	\$150.00
3.	
4.	
5.	
6.	
<b>TOTAL</b>	<b>\$200.00</b>
<b>Debit Note Total</b>	<b>\$218.00</b>

DISBURSEMENTS	AMOUNT
1. DUPL	\$4.00
2. POST	\$4.00
3. OH	\$10.00
4.	
5.	
6.	
<b>TOTAL</b>	<b>\$18.00</b>

## Office Action Summary



Application No.

10/191,430

Applicant(s)

PEET ET AL.

Examiner

Phyllis G. Spivack

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 42-89 is/are pending in the application.
- 4a) Of the above claim(s) 52-59 and 62-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 42-51, 60, 61 and 67-89 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/492,741.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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Claims 43, 75, 76 and 80-83 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants are required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. Claim 43 directed to "identifying a subject" does not further limit the subject matter of independent claim 42 from which it depends.

Claims 50 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The recitations in claims 50 and 51, respectively, "an appropriate bioavailable EPA derivative which raises EPA levels in the subject" and "EPA in the form of a 2-substituted derivative or other derivative which reduces the rate of oxidation without impairing its biological activity" render the claims indefinite. The metes and bounds of these "derivatives" cannot be precisely determined. Applicants should recite the EPA compounds contemplated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 42-51, 60, 61, 67-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaddadi, K. S., U.S. Patent 5,837,731, or Horrobin et al., U.S. Patent 6,555,700.

Art Unit: 1614

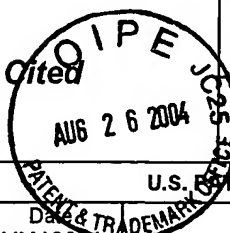
Vaddadi teaches the administration of eicosapentaenoic acid (EPA) to treat Huntington's disease. See the top of column 3 where EPA is disclosed as a member of the essential fatty acid families that may be added to  $\gamma$ -linolenic acid. Further, useful forms are free fatty acids, salts, glycerides, esters, diesters and phospholipids. The open language of the present claims does not preclude the addition of other active ingredients in the treatment. Horrobin also teaches the administration of fatty acids as EPA in the form of the free acid, phospholipid, ester and triglyceride, in the treatment of Huntington's disease. See column 15, lines 12-48, column 16, lines 47-48, and column 18, lines 18 and 32. The claims differ in that there is no recitation "of all the fatty acids present in the preparation at least 90% is in the form of EPA". However, in view of the teaching of Vaddadi or Horrobin, one skilled in the art of formulation chemistry would have been motivated to prepare and administer compositions comprising EPA that is essentially pure. Such would have been obvious in the absence of evidence to the contrary because where EPA is utilized it would have been reasonable to expect an amount approaching purity of EPA would be desired. Determinations of exact concentrations of EPA or types of other fatty acids, as well as optimal dosage forms, dosing regimens and dosages are parameters well within the purview of those skilled in the art through no more than routine experimentation. Multiple drug therapy in the treatment of Huntington's disease is conventional.

No claim is allowed.

Any inquiry concerning this communication should be directed to Phyllis G.

Spivack at telephone number 571-272-0585.

<b>Notice of References Cited</b>	Application/Control No. 10/191,430	Applicant(s)/Patent Under Reexamination PEET ET AL.	
	Examiner Phyllis G. Spivack	Art Unit 1614	Page 1 of 1



**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-6,555,700	04-2003	Horrobin et al.	554/227
	B	US-5,837,731	11-1998	Vaddadi, Krishna S	514/560
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

**FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
 Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.